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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/747,619 12/22/00 RYAN

W 1003-015

EXAMINER

025215 HM12/0410
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MCCAA, T	
ART UNIT	PAPER NUMBER

1641

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/747,619

Applicant(s)

RYAN ET AL.

Examiner

Terri L Ivory - McCaa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 12-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-11, 35-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1,5-11,35-38, drawn to a reagent composition comprising lipoprotein and a lytic agent, classified in class 435, subclass 17.
- II. Claims 2,12-16, drawn to a reagent composition comprising a lipoprotein saponin and a preservative, classified in class 436, subclass 18.
- III. Claims 3, 17-25, drawn to a reagent composition comprising lipoprotein, saponin, diazolidinyl salt and a halide salt, classified in class 435, subclass 128.
- IV. Claims 4,26-34, drawn to a method for preparing a blood sample for fluorescent analysis, classified in class 436, subclass 66.

2. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are compositions. Group I is a reagent composition for preparing leukocytes for flow cytometric analysis comprising a lipoprotein, and a lysing agent, group II is a reagent composition for preparing leukocytes for flow cytometric analysis comprising lipoprotein cholesterol, saponin and a

preservative, while group III is a reagent composition for preparing leukocytes for analysis by flow cytometric analysis comprising lipoprotein, saponin, diazolidinyl urea and halide salt. These inventions are unable to be used together because of their different ingredients which contributes to a different function and effect, therefore, for reasons set forth above, these inventions are patentably distinct.

3. Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of group IV can be practiced with another materially different product such as a composition which does not require a lipoprotein as claimed in groups I-III.

4. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mr. Eric Dobrusin on March 23 2001 a provisional election was made with traverse to prosecute the invention of group I, claims

1,5-11, 35-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2-4 and 12-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

7. The brief description of drawings is not clear as to precisely what is being represented in each drawing. Please clearly explain what is being represented in each figure.

Drawings

8. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 5 and 9 are vague. The phrase "effective amount" is not clear as to what amount is effective.
11. Claims 7 and 8 are indefinite because "said preservative" lacks antecedent support.
12. Claim 35 is vague and confusing. It is not clear as to what type of sample preparation instrument is involved with the flow cytometer.
13. Please correct missed spelled word in Claim 36 line 20 "antogen" to – antigen--.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5,9-11 & 35 rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (U.S.Patent 5,529,933).

Young teaches an aqueous suspension for blood cells comprising high density lipoprotein, and a lytic agent such as ,Saponin, and a physiological salt (Col. 8, Lines

23-27, col. 9 Line 2). The cells are analyzed by a Coulter counter (flow cytometer)(
Col. 10 , Line 8).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Ledis et al U.S.Patent 5,731,206 in view of Ryan U.S. Patent 5,270,208.

Ledis teaches a reagent system for analysis of leukocytes. The reagent comprises a lytic reagent such as saponin . The saponin is effective for reducing the size of the red cell fragments (Col.7, Lines 45-56). The lytic agent is quenched by adding salts to the sample. The salt returns the cells to their physiological environment (Col. 8, lines 24-27).

Ledis does not teach addition of lipoprotein into cell reagent.

Ryan teaches a reagent for white blood cell hematology. The reagent consists of a physiological salt solution and a high or low density lipoprotein which is useful in maneuvering the white blood cells to a correct position in the histogram (Col.3, Lines 30-68 and Col. 4. Lines 5-15).

It would have been obvious to one of ordinary skill in the art to incorporate into the reagent of Ledis lipoprotein taught by Ryan because Ryan teaches that the

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lipoprotein gives a histogram profile which mimics the white cell histogram for whole blood (Col. 3, line 60).

16. Claims 6-8,36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view Ryan U.S.Patent 5,811,099.

See discussion of Young set forth above. These references differ from the instant invention in failing to teach a preservative for cells.

Ryan discloses a direct immunofluorescence staining of cell surfaces by binding fluorescent labeled monoclonal antibodies to the surface of the cell and analyzing the fluorescence by flow cytometry (Col. 11, example XIV). Ryan also discloses a reagent for fixing cells and tissues comprising an active agent (preservative). These active agents consists of diazolidinyl urea and imidazolidinyl urea. These preservatives and stabilizer agents are non flammable and are reduced in toxicity, therefore handling and disposal would be less of a problem (Col. 4, Lines 16-19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate into the invention of Young et al, a preservative or active agent as taught in the method of Ryan because Ryan teaches that this active agent is non-flammable and less toxic to cells, therefore, this alleviates any problems associated with disposal and handling of the substance (Col. 4, Lines 16-23).

Conclusion

17. Claims 1,5-11,35-38 are not allowed.
18. The prior art made of record and not relied upon is considered pertinent to applicants disclosure.

- a. Leif et al USP 5188935;
- b. Jackson et al USP 5776709;
- c. Ryan USP 5196182;
- d. Chang et al USP 4902613;
- e. Chang et al USP 4654312;
- f. Ryan USP 5250438.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L Ivory - McCaa whose telephone number is 703-605-1207. The examiner can normally be reached on M-F 8:30-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Terri Ivory – McCaa
Patent Examiner
Art Unit 1641
April 9, 2001


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/09/01